Exhibit O

UNITED STATES DISTRICT COURT
SOUTHERN DISTRICT OF NEW YORK

PHARMACEUTICAL SOCIETY OF THE STATE OF NEW YORK, INC., STILL'S PHARMACY, INC., RIIS-WALD PHARMACY, INC., AND M.F.K. DRUG CO., INC.,

Plaintiffs,

-against-

MARIO CUOMO, Governor of the State of New York, and CESAR A. PERALES, Commissioner, New York State Department of Social Services,

Defendants.

AFFIDAVIT

76 Civ 5080 (KTD)

State of New York)
ss.:
County of Albany)

MICHAEL FALZANO, being duly sworn, deposes and says:

1. I have succeeded Mary Alice Brankman as Director of the Bureau of Ambulatory Services, Inpatient Care, and Contracts in the Division of Medical Assistance. The Division is the unit in the New York State Department of Social Services ("DSS") which is responsible for administering the Medicaid program in New York. I am familiar with both federal and state policy concerning the reimbursement of pharmacists who are Medicaid providers. I make this affidavit on behalf of defendants, Governor Mario Cuomo and Cesar A. Perales, DSS' Commissioner (collectively, the "State"), in opposition to the motion made by plaintiffs, the Pharmaceutical Society of the State of New York, Inc., Still's Pharmacy, Inc., Riis-Wald Pharmacy, Inc. and M.F.K. Drug Co., Inc. (collectively, the "Pharmaceutical Society"),

for an order requiring the State to comply with paragraph 8 of a stipulation of settlement, which was entered into by the Pharmaceutical Society and the State and which was so ordered by the Court on July 5, 1978 (the "Settlement Order").

2. I do not wish to burden the Court by annexing exhibits to my affidavit where they have previously been supplied to the Court. Instead, I reference to affidavits previously filed with the Court.

3. At this juncture, I assume that the Court has some familiarity with the federal regulations which govern the reimbursement of prescription drugs under the Medicaid program. I offer a very summary description here. These regulations establish the limits of federal financial participation ("FFP") in the costs of drugs paid for by states under the Medicaid program. Specifically, they provide that no FFP is available for those costs of "multiple source" drugs which exceed a federally established aggregate upper limit ("AUL") and that FFP for the category of "all other drugs" is limited to the drug's estimated acquisition cost ("EAC"), which is to represent the best estimate of the actual cost of the drug to the pharmacy.

4. Additionally, I assume that the Court is generally aware of the contents of the Settlement Order. (It is annexed as Exhibit A to the affidavit of Barrie L. Goldstein, sworn to on February 11, 1991 (the "Goldstein aff.") and filed in support of the State's motion to join the federal government as an indispensable party.) The paragraphs of the Settlement Order which must be considered in connection with the Pharmacutical Society's present motion are: (A) Paragraph 4 which requires the State to determine EAC on the basis of a drug's average wholesale price ("AWP"); (B) Paragraph 8 which instructs the State "to review and adjust the

accuracy...of...prices...monthly, if possible, but in no event less often than quarterly"; and (C) Paragraph 10 which exempts the State's compliance with the Settlement Order's other provisions when "mandated by Federal law...or by State law."

5. In support of its latest argument that the State has violated the updating provisions of paragraph 8 of the Settlement Order, the Pharmaceutical Society relies upon a new federal law, Section 1927(f) of the Omnibus Budget Reconciliation Act ("OBRA"), which provides:

> (1) No reductions in reimbursement limits. - (a) During the period of time beginning on January 1, 1991, and ending on December 31, 1994, the Secretary may not modify by regulation the formula used to determine reimbursement limits described in the regulations under 42 CFR 447.331 through 42 CFR 447.334 (as in effect on the date of the enactment of the Omnibus Budget Reconciliation Act of 1990) to reduce such limits for covered outpatient drugs. (b) During the period of time described in subparagraph (A), any State that was in compliance with the regulations described in subparagraph (A) may not reduce the limits for covered outpatient drugs described in subparagraph (A) or dispensing fees for such drugs.

According to the Pharmaceutical Society, OBRA preempts a new state law, 1990 N.Y. Laws, Chapter 938, Section 36 (the "updating law"), which provides that the State shall review and adjust drug prices on a bi-annual basis. As demonstrated below, no preemption occurs. First, the updating law does not "reduce reimbursement levels--the sole proscription contained in OBRA. Second, the State is not in compliance with 42 C.F.R §§447.331 through 447.334 and, therefore, OBRA does not apply.

The Updating Law Does Not Reduce Reimbursement Limits

6. OBRA instructs that states in compliance with the aforementioned regulations governing reimbursement of prescription drugs may not reduce "reimbursement limits". This is a term which the federal government uses to refer to the upper limit drug prices under Medicaid.

7. The updating law makes no change in the State's pricing of upper limit drugs nor in its pricing methodology in general. Pursuant to the Settlement Order, the State continues to determine prices on the basis of AWP.

8. Rather, the updating law only modifies the frequency for the State's review and adjustment of prices. Thus, the review and adjustment occurs bi-annually instead of monthly. Accordingly, the updating law does not conflict with OBRA.

The State Is Not In Compliance With the Applicable Federal Regulations

9. Even if the updating law could be construed as the Pharmaceutical Society suggests, OBRA would not be applicable because the State is not in compliance with 42 C.F.R. §§447.331 through 447.334, the regulations governing reimbursement of prescription drugs.

10. Under the Medicaid program, states are obligated to submit plans for approval by the Health Care Financing Administration ("HCFA"), a component of the United States Department of Health and Human Services ("HHS") (collectively the "federal government"). States then administer or supervise the program subject to review by the federal government.

11. Generally, the federal government reviews whether states are in compliance with federal laws and regulations and issues quarterly compliance reports. See 42 C.F.R. §430.32. These quarterly compliance reports cite areas where states are not in compliance. If states do not correct these deficiencies, the federal government is authorized to deny FFP for the costs of all services provided by the

state, or a portion of such costs as determined by HCFA. See 42 CFR §430.35.

12. By letter dated September 17, 1985, Theodore Shulman, Associate Regional Administrator of HHS, wrote to Commissioner Perales and informed him that the State was not in compliance with the federal drug reimbursement regulations and that changes in the State's drug reimbursement system were in order. See Exhibit A to affidavit of Mary Alice Brankman, sworn to December 19, 1989, and submitted in reply and in opposition to plaintiffs' cross-motion to modify (the "Brankman aff."). HHS demanded that the "state... implement Medicaid drug pricing levels which reflect more accurately than AWPs [average wholesale price] the prices that pharmacists are generally paying for drugs". To date, the State has been unable to comply with this demand because, as stated above, paragraph 4 of the Settlement Order establishes a drug payment methodology which calculates EAC for all drugs based on the AWP.

13. Subsequently, by letter dated June 20, 1989, Arthur J. O'Leary, HHS Associate Regional Administrator, wrote Jo-Ann Costantino, DSS Deputy Commissioner of the Division of Medical Assistance. See Brankman aff. at paragraph 18. Administrator O'Leary pursued the compliance problem which his agency initially had raised four years earlier. He told Deputy Commissioner Costantino that the "EAC methodology was not acceptable" and that the State should determine estimated costs more accurately. Id., Exhibit B.

14. By letter dated October 2, 1989, the State advised the federal government that the State was unable to revise its method of calculating estimated drug costs due to this litigation.

15. The State's compliance problems have now become exacerbated. Thus, the federal government recently reviewed the State's compliance with federal mandates for the quarter that ended on December 31, 1990. They found that New York was not in compliance with the federal drug reimbursement limitations set forth in 42 CFR §447.331 through 42 CFR §447.334. By letter, dated January 22, 1991, HCFA officially informed the State of its noncompliance. See Exhibit G to the Goldstein aff.

16. The series of warnings and the official compliance letter for the quarter ending December, 1990 clearly demonstrate that the State is not in compliance with federal drug reimbursement regulations as required for the OBRA provisions cited by the Pharmaceutical Society to apply to the State. Furthermore, these warnings and the official compliance notice require immediate resolution of this compliance issue. If the State does not conform its payment system for prescription drugs to federal drug reimbursement requirements and amend its State Plan to reflect such change, it can be expected that HCFA will begin to deny FFP for all drug payments made under Medicaid.

Michael Falzano

Michael Falzano

Sworn to before me this
15 st day of March, 1991

Notary Public
State of New York
My Commission Expires

KAREN LEE HAZZARD
Notary Public, State of New York
Qualified in Kings County
Commission Expires Jul 30, 1992